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EXAMINER	
DINH, BACH T	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,708	SHIRAKI ET AL.	
	Examiner	Art Unit	
	BACH T. DINH	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/16/2010 has been entered.

Summary

2. This is the response to the communication filed on 02/16/2010.

3. Claims 1-12, 14-19 and 21-24 remain pending in the application.

4. The application is not in condition for allowance.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-12, 14-19 and 21-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,651,595. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the U.S. Patent No. 7,651,595 and current application recite the analytical tool and analytical apparatus; wherein, the analytical tool comprises the disturbing-noise countermeasure electrode that has a noise inputting exposed portion.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawanaka et al. (WO99/05516) with equivalent English translation provided by Kawanaka et al. (US 6,599,406) with further evidence provided by Oura et al. (US 2006/0042942) and Neel et al. (US 6,743,635).

Independent claim 1 recites "an analytical tool to be mounted to an analytical apparatus" and subsequent dependent claims recite "the analytical tool". Therefore, patentability of the analytical tool is determined based on the structure of the analytical tool itself and not the way in which the analytical tool is mounted to the analytical apparatus or the structures of the analytical apparatus or the effects on the analytical tool when the analytical tool is mounted to the analytical apparatus.

Addressing claim 1, Kawanaka discloses an analytical tool, comprising:

A substrate 10 (figure 6) including a first edge end and a second end edge opposite each other (front and back end edges, figure 6);

Electrodes 146 and 117 extending between the first and second end edges;

A reagent portion 147 formed on the substrate adjacent to the first end edge (front end edge);

The exposed portion of the electrode 146 is disposed closer to the back end edge of the substrate than the exposed portion of the electrode 117 (figure 6);

Kawanaka further discloses the electrode 146 is a negative terminal (13:1-8) which is connected to the counter electrode (10:28-34) and the electrode 117 is the positive terminal which is connected to the measuring electrode (10:28-34). Moreover, the terminal 146 is grounded via the electrodes 104 and 103 when the test strip is connected to the apparatus 131 (13:26-34, figure 4).

Neel discloses a grounded counter electrode also discharge stored charges (14:60-62). The evidence provided by Neel shows that the grounded counter electrode 146 of Kawanaka is capable of functioning as the claimed disturbing-noise countermeasure electrode with the electrode 117 serving as the measuring electrode.

Oura discloses a blood glucose sensor (figure 7); wherein, the electrodes 81 and 82 are exposed in the flow channel and at the terminal ends 91 and 92, respectively (figure 7). Furthermore, the exposed portion are subjected to static electricity when the test strip 8 is mounted manually into the measuring apparatus 9 [0003-0005]; therefore, in the biosensor of Oura the exposed portions of the electrodes 81, 82 in the flow channel and at the terminal ends 91 and 92 are the noise inputting exposed portion for allowing input of static electricity.

Kawanaka discloses in figures 25-28 that an insulating layer covers the electrodes except a part of the measuring and counter electrodes that are exposed to the sample solution and the terminal ends of the working and counter electrodes are also exposed (30:27-51). Therefore, as evidenced by Oura, the exposed portions of the counter electrode for contacting the analyte and at the terminal end are capable of allowing the input of static electricity. Hence, the exposed portions of the counter electrode are the noise inputting

exposed portion of the disturbing-noise countermeasure electrode for allowing input of static electricity.

The evidence provided by Neel and Oura shows that the counter electrode of Kawanaka is structurally equivalent to the claimed disturbing-noise countermeasure electrode for the counter electrode has the exposed portions that allow the input of static electricity and is capable of discharge stored charges.

Addressing claim 2, Kawanaka discloses the electrode 117 is the measuring electrode and the electrode 146 is the counter electrode as discussed above; therefore, the counter electrode 146 is capable of applying voltage to a target portion in cooperation with the electrode 117.

Addressing claims 3-4, the subject matter of current claims are not given weight because they are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself. However, Kawanaka discloses the electrode 146 is grounded (figure 4, 13:26-34) and when switches 132 and 133 are at the open positions the electrode 146 is disconnected from the analysis circuit when the analytical tool is amounted to the analytical apparatus.

Addressing claim 19, the subject matter of current claim does not further structurally limit the apparatus of the analytical tool for it is directed to the mounting of the analytical tool to the analytical apparatus. See the discussion of claims 3-4 above. However, if the limitation of current claim is given due consideration, because the electrode 146 is located closer to the second end edge of the substrate than the electrode 117, it is inherent that the electrode 146 would come into contact with the terminals of the analytical apparatus earlier in comparison to the electrode 117.

Addressing claim 24, Addressing claim 24, Kawanaka discloses a combination of an analytical tool (test strip 145, figure 6) and an analytical apparatus (131, figure 4), the analytical tool being mounted on the analytical apparatus for analysis;

The analytical apparatus 131 comprising a plurality of terminals (104, 102 and 103) and an analysis circuit (figure 4), the plurality of terminals including a voltage applying terminal 102 and a grounding terminal 103;

The analytical tool comprising a plurality of electrodes (146 and 117 in figure 6) including a working electrode 117 (see rejection of claim 1 above) and a grounding electrode 146 as a disturbing-noise countermeasure electrode (please see rejection of claim 1 above);

Wherein the disturbing-noise countermeasure electrode includes an exposed connection end and a noise inputting exposed portion for allowing input of static electricity (please see the rejection of claim 1 above);

Wherein when the analytical tool is mounted to the analytical apparatus, the electrode 146 comes into contact with the grounding terminal 103 earlier than the working electrode 117 comes into contact with the voltage applying terminal 102 (figures 4 and 6, the electrode 146 is located closer to the back end edge of the test strip than the working electrode 117; therefore, it is inherent that the electrode 146 would come into contact with the terminals 103 and 104 before the working electrode 117 would come into contact with the terminal 102).

9. Claims 11-12 and 14-18 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kawanaka et al. (WO99/05516) with equivalent English translation provided by Kawanaka et al. (US 6,599,406) with further evidence provided by Oura et al. (US 2006/0042942) and Neel et al. (US 6,743,635).

Addressing claim 11, in figure 33, Kawanaka discloses a flow path 9 and an air vent provided in the cover 8 (12:48-60, the test strip 145 has the same configuration as the test strip 1 disclosed in figure 33). Although the biosensor shown in figure 33 is labeled as prior art, it is Examiner's interpretation and position that the flow path 9 and air vent (the combination of the channel 9 and the aperture on layer 8 constitute the air vent) of figure 33 are applicable to and present in the biosensor shown in figure 6 of Kawanaka.
In the alternative, at the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor in figure 6 of Kawanaka with the flow path 9 and the air vent as shown in figure 33 because doing so would allow one to facilitate

the movement of blood via the capillary action provided by the flow path 9 and the air vent 8 (Kawanaka, 1:63-2:8).

Addressing claim 12, in figure 33, Kawanaka discloses the counter electrode 6 is connected to the air vent; therefore, any disturbing noise coming through the air vent would inherently come into contact with the counter electrode. Hence, Kawanaka discloses the claimed input portion according to the claim language. Alternatively, in the modification discussed above, the counter electrode of the biosensor in figure 6 being connected to the air vent would inherently come into contact with any disturbing noise coming through the air vent.

Addressing claims 14-16, Kawanaka discloses the counter electrode is covered by the insulating layer except for the portion 272 where the electrode comes into contact with the analyte (30:27-36).
In figure 33, Kawanaka discloses the exposed portion of the counter electrode 6 or the noise inputting exposed portion is provided directly below the air vent (the combination of the channel 9 and the aperture of layer 8 constitute the air vent; therefore, the exposed portion of counter electrode 6 is provided directly below the air vent).
With respect to the limitation of claims 15-16, the combination of layers 7 and 8 constitute the cover which is bonded to the substrate and in which the air vent is formed and the exposed portion of the counter electrode surrounds the air vent (figure 33).

Addressing claims 17-18, in figure 33, the counter electrode 6 surrounds the working electrode 5. Therefore, due to the fact that Kawanaka focuses more on the arrangement of the terminal ends of the electrodes, Kawanaka does not disclose in detail the arrangement of the counter electrode and the working electrode in figure 6. Therefore, it is Examiner's position that the counter electrode in figure 6 surrounds the working electrode in the manner shown in figure 33.

In the alternative, it would have been obvious for one with ordinary skill in the art to modify the biosensor of figure 6 to have the counter electrode surrounds the working electrode in the manner shown in figure 33 because doing so would allow one to obtain a biosensor that is still capable of measuring the concentration of glucose. Furthermore, the counter electrode of figure 33, separate or in combination, would not have performed a materially different function when surrounding the working electrode.

Regarding the limitation of claim 18, in figure 33, the counter electrode 6 is formed along an edge of the substrate; therefore, the counter electrode 6 is formed along a periphery of the substrate as required by current claim.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-12, 17-19 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Neel et al. (US 6,743,635) with further evidence provided by Oura et al. (US 2006/0042942).

Independent claim 1 recites "an analytical tool to be mounted to an analytical apparatus" and subsequent dependent claims recite "the analytical tool". Therefore, patentability of the analytical tool is determined based on the structure of the analytical tool itself and not the way in which the analytical tool is mounted to the analytical apparatus or the structures of the analytical apparatus or the effects on the analytical tool when the analytical tool is mounted to the analytical apparatus.

Addressing claim 1, Neel discloses an analytical tool (figures 1-3), comprising:

A substrate 18 including a first end edge 12 and a second end edge 14 opposite the first end edge;

A plurality of electrodes formed on the substrate (electrodes 22, 24, 28 and 30), extending between the first end edge and second end edge (figure 2); and

A reagent portion 90 formed on the substrate adjacent to the first end edge of the substrate (figure 3);

The limitations "serves as a disturbing-noise countermeasure electrode … comparison with the electrodes other than said at least one of the electrodes" and "another of the electrodes serving as a working electrode" are drawn to the intended use of the electrodes, which do not further limit the structure of the claimed analytical tool. However, if the above limitations are given due consideration, Neel discloses electrodes 28 and 30 are grounded to discharge stored charges (15:37-39); therefore, the electrodes

28 and 30 are capable to discharging the static stored by the analytical tool. Hence, the electrodes 28 and 30 are capable of serving as the claimed disturbing-noise countermeasure electrode. Moreover, Neel discloses the electrode 22 is capable of serving as the working electrode (5:60-64).

Neel discloses leads 36 and 38 of the electrodes 28 and 30 are located closer to the edge 14 of the substrate 18 than the lead 32 of the electrode 22 (figure 2); furthermore, the leads are exposed (figures 1 and 3). Additionally, the electrodes 28 and 30 are exposed within the flow channel (figure 2).

Oura discloses a blood glucose sensor (figure 7); wherein, the electrodes 81 and 82 are exposed in the flow channel and at the terminal ends 91 and 92, respectively (figure 7). Furthermore, the exposed portion are subjected to static electricity when the test strip 8 is mounted manually into the measuring apparatus 9 [0003-0005]; therefore, in the biosensor of Oura the exposed portions of the electrodes 81, 82 in the flow channel and at the terminal ends 91 and 92 are the noise inputting exposed portion for allowing input of static electricity.

Hence, as evidenced by Oura, the exposed portions of electrodes 28 and 30 in the channel and the exposed terminal ends are the structure equivalence of the noise inputting exposed portion for allowing input of static electricity.

Addressing claim 2, the limitations "serving as the working electrode to be connected to the analysis circuit", "for applying voltage to a target portion in cooperation with the first electrode" and "serves as the disturbing-noise countermeasure electrode" are drawn to the

intended use of the electrodes, which do not further limit the structure of the claimed analytical tool. Neel discloses the electrode 22 is capable of functioning as the working electrode (5:60-64) and either electrodes 28 or 30 is the claimed second electrode.

Addressing claims 3-4, the subject matters of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself. However, Neel discloses the electrodes 28 and 30 are grounded (15:37-39). Furthermore, figure 18 discloses the contact 242 is electrically connected to the electrode 30 (19:55-57); therefore, when the switch 430 is in the open position, the electrode 30 is not being electrically connected to the analytical apparatus.

Addressing claim 5, Neel discloses a first electrode 22, a second electrode 24 and a third electrode (either electrode 28 or 30, figures 1-3). The limitations that are drawn to the intended use of the above electrodes are not given weight for the same reason addressed in the rejection of claim 2.

Addressing claims 6-7, the subject matters of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of

claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself. However, Neel discloses the electrodes 28 and 30 are grounded (15:37-39). Furthermore, figure 18 discloses the contact 242 is electrically connected to the electrode 30 (19:55-57); therefore, when the switch 430 is in the open position, the electrode 30 is not being electrically connected to the analytical apparatus.

Addressing claim 8, Neel discloses a first electrode 22, a second electrode 24 and a third electrode (either electrode 28 or 30, figures 1-3). The limitations that are drawn to the intended use of the above electrodes do not further structurally limit the analytical tool for the same reason addressed in the rejection of claim 2. Neel further discloses the electrode 24 is grounded (14:60-62).

Addressing claims 9-10, the subject matters of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself. However, Neel discloses the electrodes 28 and 30 are grounded (15:37-39). Furthermore, figure 18 discloses the contact 242 is electrically connected to the electrode 30 (19:55-57); therefore, when the switch 430 is in the open position, the electrode 30 is not being electrically connected to the analytical apparatus.

Addressing claim 11, Neel discloses a flow path 88 (figure 3) and an air vent (break 84) for discharging air from the flow path (6:64-67).

Addressing claim 12, the exposed portions 60 or 62 of either electrodes 28 or 30, respectively, in figure 2 is the claimed input portion.

Addressing claim 17, in figure 2, the electrodes 28 and 30 surround the electrode 48.

Addressing claim 18, in figure 2, the electrodes 28 and 30 are formed at the edge of the substrate at the distal end 14; therefore, the electrodes 28 and 30 are formed at a periphery of the substrate as required by current claim.

Addressing claim 19, the subject matter of current claim does not further structurally limit the apparatus of the analytical tool for it is directed to the mounting of the analytical tool to the analytical apparatus. See the discussion of claims 3-4 above. However, if the limitation of current claim is given due consideration, because the electrodes 28 and 30 are located nearer to the distal end 14 than other electrodes, it is inherent that the electrodes 28 and 30 would come into contact with the analytical apparatus earlier in comparison to the other electrodes.

Addressing claim 24, Neel discloses a combination of an analytical tool 10 (figures 1-3) and an analytical apparatus 200 (figure 18), the analytical tool being mounted on the analytical apparatus for analysis:

The analytical apparatus comprising a plurality of terminals (236, 238, 240, 242, 244 and 246), the plurality of terminals including a voltage applying terminal 236 (19:38-54) and a grounding terminal 242 (figure 18);

The analytical tool comprising a plurality of electrodes (electrodes 22, 24, 28 and 38 in figure 2) including a working electrode 22 and a grounding electrode 30 (figure 18, the electrode 30 is grounded via the contact 242, 19:61-63) serving as a disturbing-noise countermeasure electrode (15:37-39, the electrode 30 is grounded to discharge stored charges as discussed above in the rejection of claim 1);

Wherein the disturbing-noise countermeasure electrode includes an exposed connection end 38 and a noise inputting exposed portion for allowing input of static electricity (please see the rejection of claim 1 above);

Wherein the analytical tool is mounted to the analytical apparatus, the exposed connection end 38 of the disturbing-noise countermeasure electrode comes into contact with the grounding terminal of the analytical apparatus earlier than the working electrode comes into contact with the voltage applying terminal (the 30 is located nearer to the distal end 14 than other electrodes, it is inherent that the electrode 30 would come into contact with the analytical apparatus earlier in comparison to the other electrodes).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawanaka et al. (WO99/05516) with equivalent English translation provided by Kawanaka et al. (US 6,599,406) in view of Neel et al. (US 6,743,635) with further evidence provided by Oura et al. (US 2006/0042942).

Addressing claims 5-10, Kawanaka discloses the plurality of electrodes include a first electrode (figure 6, the working electrode that is connected to the terminal 117) to be connected to the analysis circuit, a second electrode for applying voltage to a target portion 147 in cooperation with the first electrode (the counter electrode that is connected to the terminal 146). As discussed above in the rejection of claim 1, the counter electrode is capable of serving as the disturbing-noise countermeasure electrode.

Kawanaka is silent regarding a third electrode which is not involved in the voltage application to the target portion and serves as the disturbing-noise countermeasure electrode.

Neel discloses a biosensor comprises a plurality of electrodes include a first electrode 22 serving as the working electrode (5:60-64) to be connected to the analysis circuit, a second electrode 24 for applying voltage to a target portion 90 (figure 3) in cooperation with the first electrode (5:60-64, the electrode 24 is the counter electrode, for applying a voltage to the working electrode, 19:50-54). Furthermore, the biosensor includes a third electrode 30 (figures 1-3), which is not involved in the voltage application to the target portion, and wherein the third electrode serves as the disturbing-noise countermeasure electrode (15:37-39, the electrode 30 is grounded to discharge stored charges; therefore, the electrode 30 is capable of serving as the disturbing-noise countermeasure electrode, please see the rejection of claim 1 under 35 U.S.C. 102(e) in view of Neel above). Additionally, Neel discloses the electrode 30 is grounded when being connected to the ground connection terminal 242 of the analytical apparatus (figure 18, 19:61-65).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor of Kawanaka with the fill detecting electrodes 28 and 30 of Neel because doing so would allow one to determine whether adequate sample is present and has mixed with the reagent layer (Neel, 5:2-26). In the modified biosensor of Kawanaka, the counter electrode and the fill-detecting electrode 30 are the second and third electrodes serve as the disturbing-noise countermeasure electrodes.

With respect to the limitations of claims 6-7 and 9-10, the subject matters of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself. However, Neel discloses the electrode 30 is grounded (15:37-39). Furthermore, figure 18 discloses the contact 242 is electrically connected to the electrode 30 (19:55-57); therefore, when the switch 430 is in the open position, the electrode 30 is not being electrically connected to the analytical apparatus.

15. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635) in view of Miyazaki et al. (WO 01/36953) with equivalent English translation provided by Miyazaki et al. (US 6,875,327).

Addressing claims 14-16, in figure 7, Neel discloses the input portions 60 and 62 of the electrodes 28 and 30 are partially covered by the insulating film 50, which includes an opening for partially exposing the input portion. Furthermore, the electrodes 28 and 30 are used for measuring whether there is a sufficient amount of sample in the test strip (15:1-11).

Neel is silent regarding the input portion is provided directly below the air vent, the cover is formed with the air vent and the input portion of the disturbing-noise countermeasure electrode surrounds the air vent.

Miyazaki discloses a biosensor; wherein, the biosensor comprises electrode 7 for measuring whether sufficient sample is present in the test strip (31:63-32:26).

Furthermore, the biosensor comprises a cover 13 with an air vent 13a and the electrode 7 is disposed directly below the air vent 13a and partially covered by the insulating film 8 (figure 1c). Moreover, from figure 1c when the air vent 13a is superimposed on the electrode 7, the electrode 7 includes a part located at the peripheral of the air vent and the exposed portion of the electrode 7 surrounds the air vent.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the test strip of Neel by having the air vent formed in the cover 72 (Neel, figure 3) and disposing the input portion of the electrodes 28 and 30 directly below the air vent with the input portion located at a periphery and surrounds the air vent in the same manner for the electrode 7 as disclosed by Miyazaki because disposing the air vent in the cover would still produce the predictable result of drawing the sample through the sample channel (Miyazaki, 15:10-11). Furthermore, modifying the test strip of Neel with the arrangement of Miyazaki would improve the accuracy and reduce the variation in response of the biosensor (Miyazaki, 4:29-39).

16. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635) in view of Rappin et al. (US 6,572,745).

Addressing claim 21, Neel is silent regarding a pinch portion.

Rappin discloses a biosensor; wherein, the side of the biosensor 310 has contour portions or claimed pinch portions located at the sides of the body (figure 13, 11:45-48).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor of Neel with the contour portions on the biosensor body

like that of Rappin because the contour portions allow easy insertion of the biosensor to the meter (Rappin, 11:45-48).

17. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635) in view of Rappin et al. (US 6,572,745) as applied to claim 21 above, and further in view of Yoshioka et al. (US 5,264,103) and Winarta et al. (US 6,287,451).

Addressing claims 22-23, Rappin discloses the pinch portion comprises a recess formed at the side edge of the test strip (figure 7, the contoured portion on the side of the test strip is the claimed recess portion).

Neel is silent regarding the electrodes 28 and 30 are covered by an insulating film except for an exposed portion adjacent to the pinch portion.

Yoshioka discloses a biosensor; wherein, the sensor comprises a main electrode system and a sub electrode system 20 comprising electrodes 8 and 9 (figure 1). The sub electrode system is for measuring the presence and the nature of the sample liquid (3:49-55) and the electrodes 8 and 9 extend along the side edges of the test strip (figure 1).

Winarta discloses a biosensor; wherein, the sensor comprises scoring line 28 of conducting material formed adjacent to the side edges of the test strip (figure 2) for reducing potential static that give rise to noisy signal (7:63-81).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the test strip of Neel by disposing the electrodes 28 and 30 along the side edges of the test strip with their respective exposed portion formed at the front end of the test strip as disclosed by Yoshioka and further disposing the electrodes 28 and 30

adjacent to the side edges of the test strip like that of Winarta because the electrodes 28 and 30 would still be able to detect the presence of the sample fluid when they are disposed in the manner disclosed by Yoshioka (figure 1) and Neel expresses that such modification is within the scope of the biosensor (8:18-37). Furthermore, disposing the electrodes 28 and 30 adjacent to the side edges like that of Winarta would allow one to reduce the potential static noise (Winarta, 7:63-8:1) when the electrode 28 and 30 are grounded (Neel, 15:37-39).

Moreover, one with ordinary skill in the art would have found it obvious to modify the insulating film 64 of Neel (figure 3) to expose a portion of the electrodes 28 and 30 at the pinch portion because exposing the electrodes 28 and 30 would allow more contact between the electrodes and potential static, thereby, reducing more of the electrical noise produced by the static (Winarta, 7:63-8:1).

Response to Arguments

18. Applicant's arguments with respect to claims 1-12, 14-19 and 21-24 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicant's arguments regarding the rejection of claim 1 as being anticipated by Kawanaka and Neel, the arguments are not persuasive for Oura is cited to show that the exposed portions of the counter electrode is capable of allowing input of the static electricity. Therefore, the exposed portions of the counter electrode of Kawanaka are the structural equivalence of the noise inputting exposed portion.

Likewise, the exposed portions of the electrodes 28 and 30 of Neel are the structural equivalence of the noise inputting exposed portion.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Champagne et al. (US 5,980,708) discloses in an electrochemical sensor, a grounded counter electrode prevents electric originating noise that would affect the working electrode (14:4-8). North discloses the sliding movement causes the non-conductive part of the sensor portion to slide against a non-conductive part of the analyzing instrument, which causes the generation of static electrical charges and associated electrical fields (2:4-10). Therefore, North further shows that the exposed terminal portion of the electrodes disclosed by Kawanaka and Neel are capable of allowing the input of static electricity.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BACH T. DINH whose telephone number is (571)270-5118. The examiner can normally be reached on Monday-Friday EST 7:00 A.M-3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

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